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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,947	03/27/2007	Katsuo Sueishi	50026/062001	2391
21559	7590			
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110				
EXAMINER				
LL BAO Q				
ART UNIT		PAPER NUMBER		
1648				
NOTIFICATION DATE		DELIVERY MODE		
07/27/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

### Office Action Summary

**Application No.**

10/598,947

**Applicant(s)**

SUEISHI ET AL.

**Examiner**

BAO LI

**Art Unit**

1648

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 1-8, 12 and 14-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-11, 13 and 17 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/S508)  
Paper No(s)/Mail Date 7/20/09
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-17 are pending.

#### ***Election/Restrictions***

1. Applicant's election without traverse of group VII, claims 9, 10, 11, 13 and 17 with species of a vector encoding a secretory protein in the reply filed on June 09, 2009 is acknowledged.
2. The restriction deems appropriate and therefore, made final. Claims, 9-11, 13, 17 are considered with the scope of an expression vector expressing a secretory protein.

#### ***Priority***

3. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on March 16, 2004.
4. However, should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).
5. Failure to provide a certified translation may result in no benefit being accorded for the non-English application.
6. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

#### ***Objection***

Claim 9 is objected to because of the following informalities:

Please spell out the complete words of PDGF-A, PDGFR $\alpha$  when they are first recited in claim. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Bergers et al. (J. of Clin. Inves. 2003, Vol. 111, No. 9, pp. 1287-1295).
9. Bergers et al. describe anti-cancer composition comprising a kinas inhibitor compound, SU6668 and/or US5416, which is specifically against PDGFR. Administration of said compound reduces the angiogenesis and tumor development (See pages 1287-1293, especially Figs. 1-2, 4-5). Therefore, the cited reference anticipates claim 9.
10. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by WO95/16032 to Meyers et al. (WO 95/16032A1).
11. Meyers et al. teach a compound, i.e. antisense nucleic acid specifically against the function of PDGFR $\alpha$  and PDGFR $\beta$ . Therefore, the cited reference anticipates claim 9.
12. Claims 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsutsumi et al. (Circulation Research 2004, pp. 1186-1194).
13. Tsutsumi et al. describe a composition comprising an expression vector, i.e. SeV that expresses extracellular domain of human PDGFR $\alpha$ . Administering such expression vector in vivo suppress endogenous PDGF-AA activity as a polyclonal antibody against PDGF-AA (See page 1187). Therefore, the cited reference anticipates claims 9-11.
- 14.

***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 9-11, 13 and 17 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 03/072704 to Mcswiggen et al. for 9-11 and 17 in view of Kusaham et al. (Gene Therapy 2002, Vol. 10, pp. 272-277) for claim 13.

17. The claimed invention is directed to a composition comprising a component against the PDGFR-A or the binding between a PDGF-A homodimer and a PDGF $\alpha$  as an active agent, wherein such agent can be expressed by an expression vector, preferably the Sendai virus vector, to inhibit tumor, preferably, an adenocarcinoma.
18. Mcswiggen et al. teach a method for treating cancer comprises using an expression vector to express an inhibitor of PDGFR A, i.e. iRNA or siRNA or RNAi or siNA in particular. Such small interference RNA can be expressed by an expression vector in tumor cells, such as prostate cancer (See pages 5-7, claims 1-32), wherein the primary prostate cancer generally belongs to adenocarcinoma that intends to over express PDGFR. However, they do not teach using Sendai viral vector to express these small RNA molecule.
19. Kusaham et al. particularly teach how to construct a Sendai virus expression vector (See entail document) that can be used for express RNA molecule.
20. Therefore, it would have been obvious for a person ordinarily skilled in the art to be motivated to make a Sendai viral vector and use it for expressing said PDGFR inhibitor and treating an adenocarcinoma, because PDGFR is predominantly over express in adenocarcinoma absence unexpected result.
21. As there are no unexpected results have been provided, hence the claimed invention as a whole is prima facie obvious absence unexpected results.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BAO LI whose telephone number is (571)272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nickol Gary can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao Qun Li/

Examiner, Art Unit 1648

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